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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/805,977	03/22/2004	Matthew Oliver Fraser	046562/274660	1508
<div>826                      7590                      02/13/2008</div> <div>ALSTON &amp; BIRD LLP</div> <div>BANK OF AMERICA PLAZA</div> <div>101 SOUTH TRYON STREET, SUITE 4000</div> <div>CHARLOTTE, NC 28280-4000</div>				
			<div>EXAMINER</div> <div>SPIVACK, PHYLLIS G</div>	
			<div>ART UNIT</div> <div>1614</div>	<div>PAPER NUMBER</div>
			<div>MAIL DATE</div> <div>02/13/2008</div>	<div>DELIVERY MODE</div> <div>PAPER</div>

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

### Application No.

10/805,977

### Applicant(s)

FRASER ET AL.

### Examiner

Phyllis G. Spivack

### Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 27 November 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 67-74, 80-88 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 67 is/are allowed.
- 6) ☒ Claim(s) 68 and 88 is/are rejected.
- 7) ☒ Claim(s) 69-74 and 80-87 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                                                                |                                                                                         |
|--------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                                               | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                           | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>8/29/07</u> | 6) <input type="checkbox"/> Other: _____                                                |

Applicants' Amendment filed November 27, 2007 is acknowledged. Claims 75-79 are canceled. Claims 67-74 and 80-88 remain under consideration.

Information Disclosure Statements filed November 29, 2007, December 4, 2007 and December 21, 2007 are further acknowledged and have been reviewed to the extent each reference has been provided and is a proper citation on a U.S. patent.

A new title and a new Abstract are noted.

A listing of co-pending applications as set forth in Applicants' Response filed November 27, 2007, is further acknowledged. The claims in the co-pending applications have been reviewed.

Applicants' arguments have been carefully considered and are persuasive. A greater than additive effect is not necessarily sufficient to overcome a *prima facie* case of obviousness. Such an effect may either be expected or unexpected. See MPEP §716.02(a). Applicants must further show that the results were greater than those which would have been expected from the prior art to an unobvious extent, and that the results are of a significant, practical advantage. In the instant case, because the currently marketed antimuscarinic drugs for lower urinary tract disorders cause a substantial number of serious side effects, the synergistic effect demonstrated by Applicants' combination appears to yield a therapeutic effect using a lower dose of the antimuscarinic agent as compared to administration of the antimuscarinic alone. It is reasonable to expect patient compliance would be improved.

Rejections and objections set forth in the last Office Action are withdrawn. The following rejection constitutes the sole rejection presently applied to the present claims.

Claims 68 and 88 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The new recitations "from about .5 mg to about 5 mg" in claim 68 and "from about .5 mg to about 2.5 mg" in claim 88 represent new matter.

Applicants refer to the first full paragraph on page 90 for support of the amendments to the claims. However, a review of the citation shows only oxybutynin is discussed, not the claimed subgenus of antimuscarinics recited in part (b) of instant claim 67. Further, ranges, as those presently recited, are not found on page 90.

Claim 67, 69-74 and 80-87 appear to be free of the prior art.

Applicants' Amendment necessitated the new ground of rejection presented in this Office Action. **THIS ACTION IS MADE FINAL.** Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this Final Action is set to expire THREE MONTHS from the mailing date of this Action. In the event a first reply is filed within TWO MONTHS of the mailing date of this Final Action and the Advisory Action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the Advisory Action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the Advisory Action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this Final Action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached from 10:30 to 7 PM.

If attempts to reach the Examiner by telephone are unsuccessful after one business day, the Examiner's supervisor, Ardin Marschel, can be reached 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

February 9, 2008

/Phyllis G. Spivack/  
Primary Examiner